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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,354	12/22/2003	Mark L. Boys	PC31766A	9317

28940 7590 11/17/2006

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,354	BOYS ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/6 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **September 06, 2006** presents remarks and arguments to the office action mailed **June 30, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of claims

Claims 1-5 are pending in this office action.

Claim 1 is allowed.

Claims 2-5 are now pending in this office action.

Specification

The abstract of the disclosure is objected to because it contains legal wording because of the word "comprising" therein. Correction is required. See MPEP § 608.01(b).

Response

Applicants remarks regarding the 112-first paragraph in the office action of record is persuasive, however, there still remains the question of enablement regarding the broad genus treating conditions mediated by $\alpha v\beta_3$ and/or $\alpha v\beta_5$ integrins. To overcome this

rejection, Applicant can incorporate the claims into the specification and limit the method of use to the treatment of kidney and or human colon carcinoma as Applicant is in possession for such.

New Claim Rejections - 35 USC § 112

Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to the treatment of a condition treated is selected from the group consisting of tumor metastasis, solid tumor growth, angiogenesis, osteoporosis, humoral hypercalcemia of malignancy, smooth muscle cell migration, restenosis, atheroscelorosis, macular degeneration, retinopathy, and arthritis. comprising administering a therapeutically effective amount of compound composition of claim 1 3-(3-tert-butyl-5-iodophenyl)-4-{3-[3-(5,6,7,8-tetranyaro-l, 8-naphthyridi- n-2-yl)propyl]-l,2,4-oxadiazol-5-yl}butanoic acid (elected specie from restriction requirement) . The specification provides no support for a variations of the diseases for the broad use of the compounds of claim 1. With regards to how to make, the claims support the that portion of the 112, however, the support if any is very general (see examples in specification), on how to use, especially how to extrapolate the assay to the treatment of the disease claimed in claims 2 and 4. Showing general mechanism (see page 250-253 of specification) does not encompass that the composition will support the broad use of treatment.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the invention state of the prior art, relative skill of those in the art and the predictability of the art.

The nature of the invention is a method of treatment of a condition treated is selected from the group consisting of tumor metastasis, solid tumor growth, angiogenesis, osteoporosis, humoral hypercalcemia of malignancy, smooth muscle cell migration, restenosis, atheroscelorosis, macular degeneration, retinopathy, and arthritis. comprising administering a therapeutically effective amount of compound composition of claim 1 3-(3-tert-butyl-5-iodophenyl)-4-{3-[3-(5,6,7,8-tetranyaro-l, 8-naphthyridi- n-2-yl)propyl]-l,2,4-oxadiazol-5-yl}butanoic acid (elected specie from restriction requirement) composition wherein the composition comprises one or more additional therapeutic agent. The nature of the invention is very broad, and the relative

skill of those in the art with expertise in the field of abnormal cell proliferative and inflammatory diseases.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy. Applicant has not conveyed that compounds of claim 1 or elected compound is that sole compound that will treat if not every disease recited in claims 2 and 4. Also Applicants have not provide highly predictive competent evidence or recognized tests to treat a wide variation of diseases or conditions recited for the claimed methods. Pharmacological activity in general is unpredictable.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples to any specific disease on how treatment is carried out with the assay data on pages 250-253 of the specification. One skilled in the art would not know how to define treatment as there is no indication of how treatment is measured. For example a control, how long treatment was carried out for it to be determined as treatment, comparison with other compounds?

The quantity of experimentation necessary

Presently, guidance as to which particular disease is contemplated according to the recited limitations in the claims is absent. In particular, with respect to methods of treating conditions mediated by $\alpha v\beta_3$ and/or $\alpha v\beta_5$ integrins, the skilled artisan would expect the interaction of the claimed compound to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for

each disease with the compounds. Absent reasonable a priori expectations of success for using the particular compound with a representation to treat any particular disease, one skilled in the art would have to test extensively many disease states to discover which show efficacy. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

State of the prior art:

See (J. Nat. Cancer Inst., Vol. 94, No. 11, 790-792, June 5, 2002.) Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat every or at most a wide variation of conditions mediated by $\alpha v\beta_3$ and/or $\alpha v\beta_5$ integrins.

Claims 2-5 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 11/13/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

SVG
5/10/06